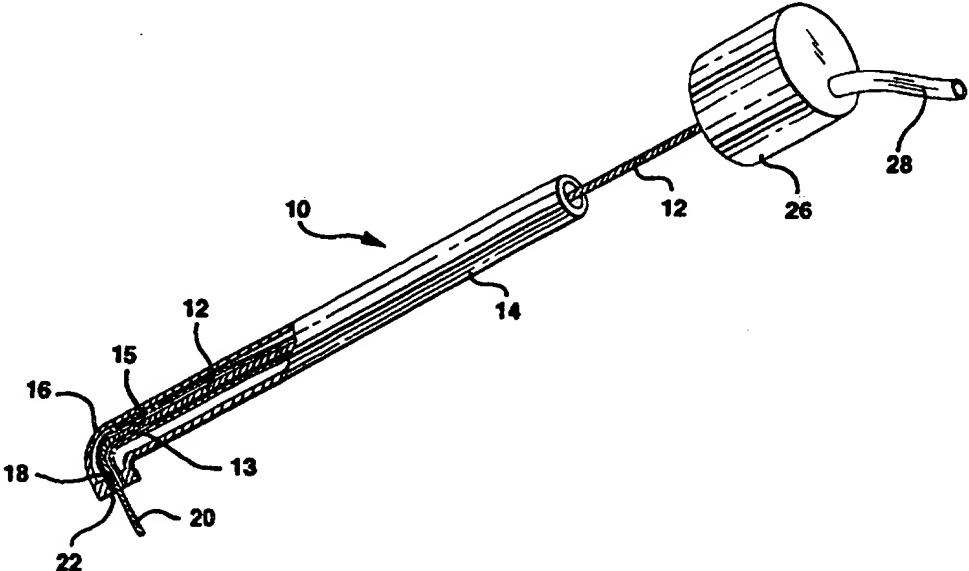




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(54) Title: FLEXIBLE CUTTING TOOL AND METHODS FOR ITS USE  (57) Abstract <p>A cable comprising helically wound superelastic fibers and having a drilling tip provided at its distal end is housed in an elongated holder through which the cable may be advanced, the holder having a distal end for supporting the cable during a drilling operation and through which the distal end of the cable may protrude. The holder includes a cable support shaped to bend the cable through a predetermined angle adjacent its distal end and to support the cable as it is rotated and advanced. A motor is attached to the cable remote from the distal end of the cable to rotate the cable in a direction tending to tighten the cable fibers.</p>		

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FLEXIBLE CUTTING TOOL AND METHODS FOR ITS USEField of the Invention

The invention relates to flexible cutting tools and to surgical drilling and other cutting procedures using such tools.

5 Background of the Invention

Modern surgical techniques often require holes or channels to be cut into bone, teeth or soft tissue, for various reasons. Holes may be drilled in bone to receive screws, sutures or bone anchors enabling anchorage of implants or reattachment of ligaments or tendons. Ordinarily, surgical drills can be employed which utilize a motor (often an air
10 motor) and a drill bit of the desired length and diameter. However, because of the proximity of other tissue or prosthetic materials, it often becomes difficult to appropriately orient a surgical drill and drill bit so that the desired bore can be formed in tissue. Dental drills are available, of course, but have generally very short bit lengths.

15 U.S. patent 5,330,468 (Burkhart) proposes a drill mechanism for arthroscopic surgery in which a rotating pin of nitinol is caused to emerge from a gently bent aiming tube, drill through a thickness of bone, and then be received in an appropriately positioned receiving tube. The device itself is somewhat bulky. Another device using nitinol pins or probes is shown in U.S. patent 4,926,860 (Stice et al.). Here, a needle
20 or other probe of nitinol may be received in a curved cannula to deliver the end of the probe to the desired location. The probe is then advanced through the cannula and exits from the cannula end in a straight orientation.

If a nitinol pin, as shown in the previously mentioned U.S. patent 5,330,468, is bent through a sharp angle and rotated at high speed, the pin becomes work hardened at
25 the area of the bend due to its constant flexing during rotation. The superelastic characteristic of the pin in that area is reduced, and the pin can readily break. Nitinol wire drills in which a nitinol pin is rapidly rotated in a sharp bend, hence, have not become commercially successful.

Summary of the Invention

We have found that an appropriate flexible cutting instrument can be obtained through the use of an elongated, flexible cutting element having a longitudinal axis about which the cutting element may be rotated, the cutting element comprising a cable or
5 bundle of parallel cables each comprising an outer layer of helically wound fibers. Cutting means is disposed at the distal end of the cutting element to perform a cutting function when the cutting element is rotated. The cables preferably are of metal and most preferably are of nitinol or other superelastic alloy. Cables of this type can withstand rapid rotation while proceeding about tight bends, without substantial work
10 hardening. A single helically wound cable can be employed, or a bundle of generally parallel cables can be used to obtain a larger diameter hole.

Because cables are far more flexible than solid pins of the same diameter, it would be expected that the distal free end (that is, the cutting end) of a cable or bundle of cables, being relatively unsupported, would tend to whip around in an uncontrolled
15 fashion when rotated rapidly. That is, a trade-off to using a much more flexible superelastic alloy cable or cable bundle would be expected to be lack of control of its drilling end. We have found that the cutting end of a flexible cutting element that is formed as cable or bundle of cables and that is slidably supported in a stationary tubular support from which the cutting end may protrude, when used as a drill, produces a bore
20 that remains relatively straight and true as the cutting element is advanced, even though the length of the cutting element that protrudes from the tube is supported only by the tissue being drilled. As long as the stationary tubular support remains in close proximity to the tissue being drilled, the tissue itself appears to provide sufficient support and guidance to the otherwise unsupported cutting end to keep it in a
25 substantially straight path.

As used herein, "tissue" refers to both soft tissue and to hard tissue such as bones and teeth.

Thus, in one embodiment, the invention relates to a cutting instrument such as a drill, the instrument comprising an elongated, flexible cutting element having a longitudinal axis about which the cutting element may be rotated and comprising a cable or bundle of parallel cables. Each cable comprises an outer layer of helically wound
5 fibers. Cutting means are provided at the distal end of the cutting element to perform a cutting function when the cutting element is rotated. A motor is attached to the cutting element remote from its distal end for rotating the cutting element about its longitudinal axis. The instrument includes an elongated holder having an opening for supporting the cutting element and through which the cutting element may be advanced axially, the
10 holder having a distal end for supporting the cutting element during a drilling operation and through which the distal end of the cutting element protrudes. The holder includes a cutting element support shaped to orient the longitudinal axis of the cutting element adjacent its distal end and to maintain such orientation as the cutting element is rotated and advanced in a cutting operation. The fibers of the cables are preferably of a
15 superelastic metal such as nitinol.

In one embodiment, the holder includes a cutting element support shaped to bend the cutting element through a predetermined angle adjacent its distal end and to maintain that bend as the cutting element is rotated and advanced in a drilling operation. In a preferred embodiment, the helically wound fibers themselves are cut at the distal end so
20 as to themselves form said cutting means.

When the flexible cutting element is formed of a single helically-wound cable, the cable is preferably so formed as to enable fibers at the distal end of the cable to separate from each other slightly under centrifugal force or axial compression or both as the cable is advanced through the holder and rotated. As a result, the diameter of the
25 drilled hole is slightly greater than the diameter of the cable adjacent but spaced from its distal end. Axial compression of the cable end against the floor of the bore causes the individual fibers of the cable to bow outwardly and thus increase the diameter of the cable at that point. A similar result is obtained when the flexible cutting element

comprises a plurality of cables arranged parallel to each other in a bundle. Here, the distal ends of the cables may separate from each other slightly under centrifugal force or under axial compression or both as the cable bundle is advanced through the holder and rotated. The diameter of the resulting hole is slightly greater than the diameter of the cable bundle adjacent but spaced from its distal end.

The invention includes a method of drilling straight holes through tissue which comprises providing the drill referred to above, rotating the flexible, elongated cutting element about its longitudinal axis while continuously maintaining the cutting means at least partially within the hole being drilled and advancing the cutting element through the holder, whereby the wall of the hole being drilled serves to support the cutting means so that the latter advances in a substantially straight path through the tissue.

A particularly preferred procedure involves a method for fastening a hollow intramedullary rod to a bone, such as the femur, within which the rod is received. Rods of this type may be employed to internally stabilize fractures of long bones such as the femur, the tibia and the humerus. The method includes the steps of providing a drill including an elongated, flexible length of superelastic alloy bearing cutting means at its distal end and an elongated holder receivable in the hollow intramedullary rod. In this embodiment, the length of superelastic alloy preferably is in the form of a cable or cable bundle as described above. The holder has a distal end for supporting the length of superelastic alloy during a drilling operation and an opening through which the distal end of the length of superelastic alloy protrudes. The holder includes a support shaped to bend the length of superelastic alloy through approximately a right angle adjacent its distal end and to maintain the bend during a drilling operation. In this procedure, the holder is positioned in the intramedullary rod, the hole through which the distal end of the superelastic alloy cable length protrudes being aligned with and referencing a preformed hole in the intramedullary rod. The length of superelastic alloy is then rotated in a drilling operation and is advanced radially outwardly from the holder through the aligned holes in the holder and rod, against and through the bone and

against and through the overlying muscular tissue and skin while continuously maintaining the cutting means at least partially within the hole being drilled. The point of exit of the drill from the skin is located, and a cannula is inserted over the cable to engage the hole through the bone. The cannula is stabilized with respect to the bone, the cable is retracted, and a drill is employed to enlarge the hole, the drill extending through the opposed wall of the bone. A screw fastener is inserted through the lateral hole thus drilled in the bone and through the preformed hole in the intramedullary rod to hold these elements together.

Other surgical uses of the instruments of the invention include dental procedures such as root canal surgery, the cleaning of osteolytic lesions resulting in bone cavities adjacent a prosthesis, the repair of anterior cruciate ligament damage, drilling holes in spinal pedicles in preparation for placing pedicle screws for spinal fusion and the like.

Description of the Drawings

Figure 1 is a broken-away, perspective view of a drill of the invention;

Figure 1A is a detailed view of the distal end of the drill of Figure 1;

Figure 2 is a broken-away, schematic view of a cutting tip of a drill of the invention shown forming a bore in bone;

Figure 3 is a schematic, broken away diagram of a leg with a broken femur, the latter being internally stabilized by placement of an intramedullary rod; and

Figure 4 is a broken-away, schematic view of a device of the invention as the same is used in connection with the intramedullary rod shown in Figure 3.

Figure 5 is a broken away, cross-sectional view of a device similar to that of Figures 1 and 2, suitable for use in connection with the intramedullary rod shown in Figure 3;

Figures 6A and 6B are broken away, cross-sectional views of a portion of the device shown in Figure 5;

Figure 7 is an exploded view, in partial cross-section, of a device for inserting a connector in an intramedullary rod of the type shown in Figure 3;

Figure 8 is a broken away, cross-sectional view of a simplified device of the invention showing particular details, and Figure 8A shows a specific cutting end;

Figures 9A, 9B and 9C are broken away, cross-sectional views of an end portion of a device of the invention showing a method of orienting the longitudinal axis of the cutting element;

Figure 10A, Figure 10B and Figure 10C are broken away, cross-sectional view showing a modified embodiment of the invention;

Figure 11 is an end view of a device of the invention of the type shown in Figures 10A, 10B and 10C, illustrating a modification of the device;

Figure 12 is a side view of a drilling device similar to that of Figures 1 and 1A and suitable for use in connection with boring holes in spinal pedicles;

Figure 13 is a schematic view of the device of Figure 12 and showing the preparation of a drill hole in a spinal pedicle for reception of a pedicle screw;

Figure 14 is an enlarged, broken-away, cross-sectional view of a portion of the device circled in Figure 12;

Figure 15 is a cross-sectional view taken along line 15 - 15 of Figure 14; and

Figure 16 is an enlarged, broken-away cross-sectional view of the portion of Figure 13 circled in that figure.

Detailed Description

The flexible cutting tool of the invention makes use of fibers, preferably of metal and most preferably of a superelastic metal alloy, in the form of a cable of helically wound fibers or a bundle of such cables arranged parallel to each other. With reference to Figure 1, a flexible cutting tool of the invention, exemplified as a drill, is shown as 10. A flexible, helically wound cable is shown generally at 12, the cable extending through the interior of an elongated tubular support 13 that itself is supported by an elongated tubular holder 14. Support 13 closely receives the cable and supports the cable against undue lateral movement or buckling even when the cable is rotated rapidly or is under torsional or axial load. The inner diameter of the tubular support 13

preferably is no more than twice the diameter of the cable, and in general, the inner diameter of the tubular support need be only about 0.001 to 0.005 inches larger than the diameter of the cable. At its distal end 16, the tubular support 13 is bent through an angle so that its inner surface 18 serves as a supporting surface to support the cable as it is oriented in a predetermined direction to exit from the side of the holder 14. In Fig. 1, the cable 12 is oriented at about 90° to the axis of the cable. Distal end 20 of the cable protrudes from the distal end 22 of the tubular support 13. It will be understood that the cable exemplified in Figure 1 may be replaced with a bundle of parallel cables, of which more will be said below.

10 A motor 26 is shown in Figure 1 for rotating the cable 12 about its axis. The motor can be any rotating driver, and may take the form of an electric motor or an air motor, the latter being driven by compressed air entering the motor through supply tube 28. Although the motor may be rotated at whatever speed is desired, speeds of about 50,000 rpm are appropriate. For certain uses, slower speeds are required. Rotational speeds can be varied from a few revolutions per minute up to 150,000 revolutions per minute or more. The motor 26 may be mounted to the proximal end of the cable 12 (or cable bundle, as the case may be) using commonly available chucking equipment, crimping techniques, or adhesive bonding. It is contemplated that the cable 12 may run through the motor 26 with the rotating portion of the motor engaging the outer walls of the cable in a manner enabling the rotating cable to be advanced axially with respect to the motor. Preferably, however, a chucking arrangement is employed in which the proximal end of the cable 12 is received in the chuck of the motor in known fashion, that is, using the chucking mechanism that is common to power drills and drill bits. With this preferred embodiment, the motor 26 is fastened to the cable 12 so that axial movement of the motor and cable distally toward the distal end of the holder will cause the end 20 of the cable to advance outwardly of the hole 22 for at least a distance equal to the depth of the desired hole. In one embodiment, the motor 26 may be mounted to

the proximal end 30 of the holder, and the holder itself, rather than being formed from a single tubular member as shown in Figure 1, may be formed of two or more tubular members that telescope together such that the length of the holder 14 can be lengthened or shortened. In this embodiment, shortening the length of the holder 14 causes the
5 cable 12 to advance distally out of the hole 22. The telescoping portions of the handle 14 may, in fact, have mating circumferential threads such that rotation of one portion of the handle with respect to the other through a given angle will result in a predetermined advancement of the distal end 20 of the cable outwardly of the hole 22.

The distal end 20 of the flexible, elongated cutting element, depicted as a single
10 cable in Figures 1 through 11, is shown best in Figure 2. The single cable, preferably of nitinol or other superelastic alloy, desirably is formed about a central core wire 32 about which are twisted a plurality of strands as shown in the drawing. Any twisted cable of the type depicted will operate, such as cables having successive layers of oppositely twisted fibers, as long as the outer layer of fibers is twisted in a direction
15 causing the fibers to wrap more tightly as the cable is rotated. Preferably, the cable contain only a single layer of twisted fibers, the twist direction being the same for each fiber. As noted previously, the flexible, elongated cutting guide may comprise a plurality of parallel cables in a bundle, as explained in greater detail below.

From Figure 2, it will be seen that if the cable is rotated in the direction shown
20 by the arrow A, the helically wound strands will tend to tighten upon one another, torque thus being readily transmitted from the motor to the distal end 20 of the cable. It will also be understood that if the cable is rotated by the motor 26 in the opposite direction, the cable will tend to untwist and become quite loose. Rotation in the direction of the arrow A in connection with the twist direction shown in Figure 2 thus is
25 important to proper operation of the drill. It should also be understood that in Figure 2, the distal end portion of the tubular support has been omitted to enable the twisted nature of the cable to be better illustrated. In practice, the cable is supported by the tubular support throughout substantially the entire length of the cable except for the

distal end portion that is received and supported in the tissue being drilled. In a similar fashion, when using a bundle of cables, it is desired that the cables each have the same twist direction, and that the bundle be rotated in a cutting operation so as to tighten the fibers in the bundles. That is, if the fibers of each bundle twist counterclockwise toward
5 the distal end of the bundle, then the motor should provide clockwise torque as viewed from the proximal end.

At its distal end, the twisted fibers forming the cable may tend to separate from each other slightly under the substantial centrifugal forces generated by the motor 26 or from axial compression of the fibers against the floor of the hole or both. Figure 2
10 shows the twisted strands separating slightly as the drill is used to form a bore 34 in a bone mass B. Note that the diameter of the bore 34 is somewhat larger than the diameter of the cable 12 spaced away from the end 20 of the cable. Here, the cable strands 33 have separated and have spread outwardly slightly so that the bore 34 is slightly larger than the cable diameter. Some clearance thus is provided between the
15 inner surface of the bore and the cable itself, and this is believed to help in preventing binding of the cable within the bore and to permit debris from the drilling operation to escape. As the rotational speed of the cable is increased, the separation of strands at the distal end of the cable increases under centrifugal force; hence, one may control the diameter of the bore through adjustment in rotational speed of the cable. The same
20 concept is applicable to the use of cable bundles: rotation of a cable bundle about the longitudinal axis of the bundle produces centrifugal force sufficient to slightly separate the individual cables of the bundle and thus to produce a bore that is slightly larger than the cable bundle spaced from its distal end.

At the distal cutting edge of the twisted fibers, it should be noted that the fibers
25 are maintained within the previous diameter of the hole and are supported by that diameter as they cut. In this manner, the hole or bore 34 itself serves as a support or guide that prevents the distal end of the cable or cable bundle from moving in an uncontrolled manner and which causes the bore 34 to remain straight. Soft tissue, such

as muscle, provides similar support.

The support 13 in the embodiment shown in Figure 1 is tubular with a central lumen 15 housing the cable and being only slightly larger than the cable 12, as discussed above, so as to permit the cable to rotate substantially freely in the holder while
5 preventing the cable as it rotates from kinking or doubling back on itself. The distal end of the holder of Figure 1 is itself oriented at predetermined angle, exemplified as an angle of 90 degrees, the surface of the lumen at the bend furnishing the support that serves to maintain the 90 degree bend of the cable as the latter rotates and advances through the holder. Various other configurations supporting the cable at its bend can be
10 employed. For example, the holder may simply be provided with an orifice at or adjacent its distal end through which the cable may be advanced, and the inner surface of the holder may be smoothly curved to support and maintain the bend in the cable. The holder may include an elongated groove, formed in an insert in the holder if desired, that houses and supports the cable for at least a portion of its length. If desired,
15 the lumen 15 may be provided with constrictions spaced along its length, the constrictions providing supporting surfaces positioned to contact and support the cable at one or more points along its length.

In the drawings, the tubular support 13 and holder 14 are shown as defining a mechanically separate device which can be received within a hollow intramedullary rod or the like. In an alternative embodiment, an intramedullary rod or the like may itself
20 define the support. For example, generally solid intramedullary rods are known in the art. Such an otherwise solid rod can be provided with an internal passage which is sized and shaped much as is the support 13 described above. In such an embodiment (not illustrated in the drawings), the intramedullary rod performs the functions of the holder
25 14 of the invention and the passage in the rod performs substantially the same function as the support detailed above.

Any suitable cutting tip can be used at the end of the cable or cable bundle. In one embodiment, one or more fibers of the cable or cable bundle may be formed as a

loop as shown at 190 in Figure 8A. When the elongated cutting element is rotated, the loop expands to thus form a bore larger than the diameter of the cable or cable bundle adjacent the loop. Also, if a loop cutting end is used, the loop may be used to pull a suture through the formed bore when the cable is withdrawn from the bore, thus
5 simplifying surgical procedures involving fastening ligaments or tendons or cartilage to bone.

As noted above, the end of the cable or cable bundle can simply be cut straight across perpendicular to its length, or may be cut so as to present cone-shaped, rounded, diagonal or oblique shapes or other configurations. The resulting sharp ends of the
10 individual fibers thus cooperate to form the drilling tip. If desired, the fibers at the distal end of the cable may be welded together to prevent them from separating under centrifugal force. Also, a separate drill bit similar to drill bits currently in use for surgical procedures can be used, the drill bit being welded, crimped, glued or otherwise fastened to the distal end of the cable. In one embodiment, the drill bit may have
15 cutting edges at its distal end but may include an axial bore formed in its proximal end sized to receive the distal end of the cable which can then be welded into the drill bit bore. Of course, whenever a separate drill bit is attached to the end of a cable, there is some risk that the drill bit may come loose during a drilling operation. As a result, it is preferred that the drill bit be formed by the ends of the strands forming the cable or
20 cable bundle, as shown in Figure 2.

The use of a highly flexible cable of the type described above in a drilling procedure also offers the advantage that the cable will follow, in a drilling operation, the softer part of material being cut. For example, root canal surgery commonly requires that a hole be drilled through the root of a tooth following the nerve canal. The nerve
25 canal of a tooth is slightly curved. Dental drills currently in use are comparatively rigid and cannot, accordingly, easily follow the deviations from straightness that are common to root canals. However, the cutting tool of the present invention, which makes use of a very flexible cable or bundle of cables, is capable of being inserted into the root canal of

a tooth and, by being gently advanced, can perform the desired cleaning and nerve removal by following the normal canal curvature, guided by hard enamel surrounding the canal. Moreover, since the depth of the hole that is drilled is dependent upon the distance through which the cable or cable bundle is advanced through the opening in the
5 handle, the end of the handle can be rested upon the surface of the tooth being drilled, and the depth of the bore in the tooth can be controlled with great accuracy. Further, since the fibers at the end of the cutting element can be caused to flare outwardly (see Figure 2), the flared fibers can be employed in a procedure to cut, dislodge and displace material beyond the ends of the roots, a procedure that is difficult when using present
10 day dental instruments.

The ability of the flexible cutting element to follow the normal curvature of a curved bone, guided by contact with cortical bone near the bone surface, can be adapted to a variety of surgical procedures. In procedures involving posterior fusion of the spine, pedicle screws combined with internal rods and clamps are an option in providing
15 stability to the spine. Placement of pedicle screws presents a significant hazard resulting from drilling screw holes through the wall of the pedicle, thereby risking damage to the spinal cord or nerve bundles extending from the spinal cord and resultant temporary or permanent paralysis. Pedicle screws are inserted into the medullary canal of the pedicle from a posterior surgical approach. The posterior lateral aspect of the pedicle may be
20 exposed for direct visualization.

The current invention allows for a percutaneous approach to the pedicle under direct visualization resulting in reduced exposure and trauma to soft tissues. The posterior aspect of the spine is exposed in a standard surgical approach. The pedicle drill is positioned over the pedicle, lateral to the spinous process, and the rotating cable
25 bundle is advanced into the medullary canal of the pedicle. The medullary canal of the pedicle is made up of cancellous bone which is significantly softer than the cortical bone making up the outer surface of the vertebra and pedicle. The flexible nature of the cable group enables the cable group to follow the path of the softer cancellous bone. The

cable group will follow this path even if the surgeon angles the cable guide tube of the pedicle drill away from the axis of the medullary canal of the pedicle, whereas a standard twist drill will create a linear hole in the direction set by the surgeon.

The present invention provides, in a preferred embodiment, a method enabling
5 accurate intramedullary rod placement and securement to a bone. With reference to Figure 3, the femur F of a patient is schematically shown as having several fractures, the bone segments being internally stabilized by means of an inserted intramedullary rod 40 having a hollow interior 42 and a series of preformed holes 44, 46 formed through its walls. The purpose of these holes is to receive bone screws that are driven from the
10 exterior of the leg inwardly through the bone wall to secure the bone to the rod.

Proper location of the holes in the intramedullary rod has been a problem. One method involves using a fluoroscope to locate the holes in the rod, and then place
Stimen pins or the like percutaneously through the femur and the corresponding holes in the rod, using the pins as guides in the subsequent placement of screws. An inherent
15 hazard of this procedure is exposure of the patient and medical staff to gamma radiation. External targeting of the rod holes without use of fluoroscopy but using instead knowledge of the hole locations with reference to the proximal (exposed) end of the rod is difficult because the rod often must bend and twist as it is impacted into the
intramedullary canal of the bone. Screws that are not properly placed need to be
20 removed and replaced, leaving an additional hole in the bone and requiring additional operating time.

According to one embodiment of the invention, this problem is approached from a different direction. Once the hollow intramedullary rod has been impacted into place in the bone, as shown in Figure 4, a drill 50 of the invention having an appropriately
25 slender shape is inserted into the rod from its proximal end and is advanced until the distal end 52 of the cable, bent through 90 degrees as shown in the drawing, can be extended through a hole 44 in the rod. The motor is activated and the cable is advanced axially to cause a hole to be drilled radially outwardly through the femur. The drilling

operation can be continued through soft tissue exterior to the femur and can, if desired, be brought outwardly of the skin, all as is described in greater detail below in connection with Figures 5 - 7.

The invention has been described above primarily with respect to the superelastic alloy nitinol, but other superelastic materials may also be used, as well as such other materials and metals such as stainless steel. Nitinol is a superelastic (sometimes referred to as pseudoelastic) material, that is, a material that can be processed or treated to exhibit superelasticity at a desired temperature such as body temperature. A number of shape memory alloys are known to exhibit the superelastic/pseudoelastic recovery characteristic, and these are generally characterized by their ability, at room or body temperature, to be deformed from an austenitic crystal structure to a stressed-induced martensitic structure, returning to the austenitic state when the stress is removed. The alternate crystal structures give the alloy superelastic or pseudoelastic properties.

A modified device of the invention is shown in Figures 5 and 6 as 60. A handle grip 62 is provided with a bore 64 within which is telescopically received a tubular housing 66. An elastically compressible helical spring 68 is positioned between opposing shoulders of the handle grip and tubular housing as shown in the drawing. Finger grip 70 is provided to enable the device to be conveniently grasped in the hand such that when the finger grip 70 and handle grip 62 are squeezed towards one another, the tubular housing 66 extends more deeply into the bore 64 to cause a cable to protrude from the instrument. At its proximal end, the tubular housing has an expanded portion 74 which houses the impeller 76 of a simple air motor which is driven from an air source (not shown) and which is capable of developing substantial rotational speeds. Speeds on the order of 40,000 - 50,000 RPM are appropriate for many drilling functions, although speeds of rotation can be varied as desired.

Extending within the bore of the tubular housing 66 is an elongated tubular support 78 having a curved distal end 80. Extending through the tubular support is a cable 82 of the type described above sheathed and clamped in a drive tube 79, the

proximal end of which is axially received in and clamped in the impeller 76 as shown in the drawing. The distal end of the cable extends beyond the distal end of the drive tube and through the bend 80 of the tubular support. It will be understood that as the finger hole 70 and handle grip 62 are squeezed together, the drive tube 79 is telescopically
5 received distally in the tubular support, causing the cable 82 to protrude further from the curved section 80. Preferably, however, the drive tube 79 is of larger inner diameter and telescopically receives within it the tubular support 78. In this manner, the tubular support 78 more closely receives and supports the cable 82

The handle grip 62, and its distal end, includes an elongated tube 84 terminating
10 in opposite, outwardly extending bosses 86, 88, the bosses being so shaped as to enter the holes 44 formed in an intramedullary rod of the type shown in Figures 3 and 4. Boss 88 has a hole formed through it as shown best in Figure 6B to receive the curved end 80 of the tubular support 78. The bosses 86 are formed on distally extending, generally parallel arms having upstanding pins 90 formed on them. A camming block
15 92 is provided with angled slots 94 within which the pins 90 are received, the slots being configured such that when the camming block is moved distally, the pins 90 and hence the bosses 86, 88 are moved together to enable the device to be removed from an intramedullary rod. On the other hand, when the camming block 92 is moved in the
20 proximal direction, the bosses are forced away from each other and into opposing holes formed in the intramedullary rod to anchor the end of the tool appropriately in the rod. A wire 91 extends from the camming block to a finger grip 72 slidably mounted at 93 to the handle grip. As the finger grip 72 is moved toward the handle grip 70, the bosses 86, 88 are caused to separate to the position shown in Figure 5. Movement of the finger grip 72 in the opposite direction causes the bosses to retract toward each other.

25 Referring again to Figure 5, the handle grip 62 includes an oblique channel 96 for fluid delivery for lubrication, irrigation or cooling, the channel having an appropriate external fitting such as a Luer fitting 98.

With reference, then, to the procedure described above in connection with Figures 3 and 4, it will be understood that the tube 84 of the handle grip 62 is sufficiently long as to extend the length of an intramedullary rod. The tube 84, with the bosses held in their retracted position by the cam block 92, is inserted into the intramedullary rod until the bosses 86, 88 are adjacent to the holes 44 in the rod. Once the bosses have entered the holes (as can readily be sensed by the surgeon), the cam block 92 is moved proximally to lock the bosses in the opposing holes in the intramedullary rod. The air motor is energized, and the cable is advanced in a drilling operation as has been described earlier.

Figure 7 depicts apparatus which can be used to place a bone screw or other connector through the bone and intramedullary rod shown in Figure 3. As noted above, the cable 82, after drilling through the wall of the femur, will continue to drill in a substantially straight path through soft tissues of the thigh and will emerge from the skin. Shown in Figure 7 is a hollow introducer rod 100 within which is received a cable clamp, the latter comprising a rod 102 received within a tubular housing 104. At its bottom end, the tubular housing 104 includes an internal rubber seal 108 to receive the end of the cable and to clamp onto the cable as the rod 102 is moved axially within the tube 104. The end of the cable protruding from the patient's skin is captured within the rubber seal 108 so that the cable may be firmly supported. The introducer rod 100 is then slid axially downwardly along the cable clamp and the cable while holding the cable in tension until the conical end 106 of the introducer rod is received in the rim of the hole in the femur through which the cable protrudes. The introducer rod is held firmly against the rim of the hole, and the cable clamp is then removed. The cable itself can be withdrawn from within the introducer rod, and the entire apparatus shown in Figure 5 can be set aside. Over the introducer rod is then advanced a guide tube 110 carrying within it a drill sleeve 109. The guide tube 110 has a convenient handle 112 to aid the surgeon in supporting the instrument. At its distal end, the drill sleeve 109 has bone seating spikes 114 which are driven into the surface of the femur around the hole

that had been drilled, following which the introducer rod is removed. At this point, a long surgical drill is inserted through the hollow center of the drill sleeve, and a hole of greater diameter is drilled through the femur, the drill bit passing through the intramedullary rod and thence through the opposite side of the femur. The drill and supporting drill sleeve are then removed, and a fixation screw (not shown) can be advanced through the guide tube 110 and fastened through the holes drilled in the femur and through the preformed holes in the intramedullary rod to firmly attach together the femur and the intramedullary rod.

Figure 8 is a broken away, largely schematic view showing details of the distal end of a device of the invention. A length of cable as described above is shown at 120, the cable and drive tube 125 (described below) slidingly being received in a tubular support 122. The tubular support is in turn axially constrained within a tubular housing 124. As shown, the cable is sheathed in a drive tube 125 which extends from a point 127 spaced from the distal end of the cable proximally into mounting engagement with the impeller. The drive tube is secured to the cable by crimping at either or both ends, by the use of an adhesive, or by other similar means. If the tubular support is received within the drive tube, then the drive tube and elongated cutting element are attached at their proximal ends. As the air motor is moved distally, that is, to the left in Figure 8, the cable 120 is advanced outwardly of the tubular support 122.

Note that the distal end of the tubular housing 124 includes a supporting element 130 having a proximal portion 132 that is received within the end of the tubular housing 124 and a nose 134 extending approximately at right angles to the housing 124.

Supporting element 130 is formed with a curved bore within which is seated the distal end 136 of the tubular support 122, the supporting element 130 holding the tubular support 122 and distal end 136 rigidly so as to properly orient the cable 120 as it emerges from the tubular support. The nose 134 may be made as narrow and tapered as desired to enable it to fit, for example, accurately against the surface of a tooth above the root, the instrument being appropriate for use now in performing a root canal

surgical procedure.

The axis of the cable or cable bundle may be oriented adjacent to its distal end through any predetermined angle ranging from 0 degrees to 180 degrees. Moreover, the elongated tubular support holder through which the cable is passed and trained about the predetermined angle may itself be adjusted before or during use. Figures 9A, 9B and 9C show a cable 140 carried by tubular support 142 within an elastically bendable tubular housing 144, the latter, if desired, being made from nitinol or other superelastic alloy. The tubular support 142 is provided with a series of spaced notches 146 cut into one side wall adjacent the distal end of the support. A control wire 148 extends within the tubular housing 144 adjacent the tubular support 142, the wire being attached to the tubular support at 150 on the same side of the tubular support as are formed the notches 146. As will now be noted from Figures 9A, 9B and 9C, as the wire 148 is pulled proximally, the walls of the notches 146 tend to pinch together and permit the tubular support 142 to bend. This, in turn, also tends to bend the distal end of the tubular housing 144, all as illustrated in the drawing.

Figures 10A, 10B and 10C illustrate another way in which the cable or cable bundle may be oriented at a predetermined angle at the distal end of a device of the invention. In Figures 10A, 10B and 10C, an elongated tubular support holder 160 is shown emerging from a tubular housing 162. The tubular support may be bent as desired as shown in 10B, and the cable 164, which is slidably received in the tubular support 160, can then be extended from the end of the tubular support. The tubular support 160 may, if desired, be bent manually by the surgeon so as to enable the distal end 166 of the support to be appropriately placed adjacent a bone or other tissue to be drilled. Alternatively, the tubular support may be of superelastic alloy having the preformed shape shown in Figure 10C, the flexible nature of the support 160 enabling it to be housed in a generally straight configuration within the tubular housing 162 as shown in Figure 10A and to protrude in a curved fashion when advanced distally within the housing 162, the curved nature of the support 160 enabling it to be steered as

desired.

As will be appreciated from the foregoing description, the apparatuses of the invention may be employed for a variety of purposes. One application involves anterior cruciate ligament reconstruction. In this procedure, a ligament graft, either a separate
5 graft or a section of the patellar ligament, is passed through a hole prepared in the tibial plateau. Proper placement of the exit site of the hole in the tibial plateau is critical to long term functioning of the graft and of the knee. If the hole is placed too far anteriorly, the graft will impinge in the femoral notch, resulting in early failure. If the hole is placed too far posteriorly, the graft will not provide the needed stability to the
10 knee.

Using conventional techniques, the distal hole in the tibia to accept the graft is drilled from an exterior antero-distal approach. With the present invention, however, a surgeon is able to start the drilling process from within the joint space, directly targeting the desired bore location with the drill. The cable is advanced distally and emerges
15 from the tibial anterior cortex distal to the joint. A cannulated drill is then advanced over the cable and into the joint space, exiting at the appropriate point on the tibial plateau. The same technique may be used to prepare the femoral drill hole from the intracondylar notch. Thus, by starting the drilling operation from inside the joint space, accurate location of the bore is made possible.

20 Osteolysis, the formation of a lesion in bone around an implant, may lead to substantial damage to the bone. Osteolytic lesions are commonly progressive, leading to loose and painful implants, fracture of supporting bones, or failure of the implant. Revision surgery is often the only available option to treat such lesions. However, the flexibility of operation that is afforded by cutting instruments of the invention may
25 enable lesions to be cleaned and filled without extensive surgery. Once a portal is drilled through the cortical bone surrounding the lesion, a cutting instrument of the type shown in Figures 10A, 10B and 10C may be advanced into the lesion cavity. As the cable is advanced into the lesion, it may be carefully controlled so as to drill away small

portions of the commonly much softer lesion material. However, if a substantial length of cable is permitted to protrude from the elongated cable holder tubular support, the end of the cable may be permitted to randomly tumble about the lesion cavity, selectively cleaning away the soft lesion material.

5 Referring now to Figure 11, a cutting instrument of the invention, as typified in Figures 10A, 10B and 10C, can be equipped with various other elongated instruments for performing different functions. Figure 11 shows the end of an instrument of the invention. Here, an outer tubular housing is shown at 170, the housing carrying within it a cable 172 and tubular cable support 174. Also carried within the housing 170 may
10 be an optical fiber bundle 176, and small tubes 178, 180 which may be employed to flush the cutting site with water or other cleaning liquid. This construction lends itself to the cleansing of osteolytic lesions as described above. The optical fiber bundle 176 permits the position of the cable to be continuously visualized as cleaning of the cavity occurs, and the tubes 178, 180 may be employed to flush away the liberated lesion
15 material. Particularly when the end of the cable is permitted to move randomly, the strands at the end of the cable may be unwound slightly to permit the strands to open up, or the wires of which serve to cut away the lesion material. Once the lesion is cleaned out, the lesion cavity may be filled with bone cement or with bone graft material. The use of bone graft material supports reformation of the bone in the lesion
20 cavity, whereas bone cement would inhibit debris from infiltrating the space and triggering another osteolytic lesion. In connection with the osteolysis procedure described above, since the end of the cable may be permitted to whip about randomly in the bony cavity that is being cleaned, the speed of rotation should, of course, be far less than the speed of rotation when the instrument is being used as a drill.

25 Although the invention has been described primarily in connection with the use of a single cable as the elongated flexible cutting element, the latter element may also take the form of a bundle of cables arranged parallel and contiguous to each other. In general, a single cable cutting element is preferred for use in forming a hole through

soft tissue, whereas a cable bundle is preferred for forming a hole in hard tissue such as bone or teeth.

A cutting element formed of a bundle of cables is designated as 200 in Figures 12 - 16. One arrangement of the cables in a bundle is shown in Figure 15, in which six
5 cables 202 surround a central cable 204. It will be understood that the number of cables will depend upon their individual diameters and the diameter of the desired bundle. A cable bundle generally will not employ fewer than 3 nor more than about 17. A bundle of seven cables, arranged with six cables surrounding a central seventh cable, each cable comprising six fibers surrounding a central seventh fiber, has given good results. Each
10 cable consists of a plurality of fibers, that is, metal wires in the preferred embodiment, twisted in a helical fashion as described above. A bundle of seven cables, arranged with six cables surrounding a central seventh cable, with each cable comprising six fibers surrounding a central seventh fiber, all as shown in Figure 15, has given good results. The cables generally will fit next to each other in a manner dictated by the number of
15 cables, the twist imparted to the fibers in each cable, the applied torque, the applied thrust, the number of fibers in each cable, etc.

Since the individual cables of a cable bundle are flexible, they will tend to twist about one another in rope-like fashion as shown best in Figures 14 and 16 when torque is applied by a motor, and in fact the bundle of cables can be supplied in this twisted
20 configuration so that this configuration is maintained when no torque load is applied. Preferably, however, the individual cables of a cable bundle, at rest, are generally straight and exhibit no significant twist around each other. In this manner, the cable bundle may be rotated in either direction, and the applied torque will impose a twisted configuration as exemplified in Figures 14 and 16 upon the bundle. This configuration
25 causes the cables to tighten upon each other under a torque load so as to readily transmit torque from the motor to the cutting element.

Figures 12-16 depict the use of an instrument of the invention in connection with a surgical procedure involving the boring of holes for the placement of pedicle screws in

vertebrae. The instrument is depicted in Figure 12 as 210 and comprises an air motor 212 driven by a source of compressed air (not shown) and housed in a housing 213, the air motor being attached to and driving the cable bundle 200 in the manner described above in connection with Figure 1. The cable bundle extends through a tube 214 carried
5 by the air motor housing, the latter tube being telescopically movable within an outer tube 216 which has a distal guide tube portion 218 of reduced diameter and through which the cable bundle slidably travels. Guide tube 218 terminates distally in a guide bushing 220 that encircles the cable bundle so as to orient and direct it in a given direction. Under centrifugal force, the cable bundle will expand in diameter into contact
10 with the bushing 220, and the clearance, at rest, between the bushing and the cable bundle may be controlled to vary the diameter of the hole to be drilled. Guide tube 218 can be bent, as noted above in connection with Figure 1, or may be straight as shown in Figures 12-16, the cable bundle issuing from the tube 218 along the longitudinal axis 219 of the cable bundle as the tube 214 is telescopically received within the outer tube
15 216. Finger grips 222 may be provided on the outer surface of the outer tube 216 to facilitate easy manipulation of the instrument. During a preferred drilling operation, the outer tube 216 is maintained stationary with the guide bushing 220 adjacent to or touching the surface of the bone in which a hole is to be drilled. The cable bundle is rapidly rotated by the air motor 212, and the tube 214 and the cable bundle are advanced
20 distally through the outer tube 216 and the guide tube 218, the cable bundle issuing distally from the end of tube 218.

Figure 13 illustrates how a bore can be drilled in a vertebra "V" to receive a pedicle screw. The body of the vertebra is shown at 230 and has an outer layer of cortical bone 232 surrounding an inner cancellous - that is, spongy - bone mass 234.
25 The vertebral foramen is shown at 236, and the pedicle at 238. The tip of the guide tube 218 is placed against the pedicle, and the cable bundle 220, being rotated rapidly by the air motor, penetrates through the cortical bone of the pedicle and enters the cancellous area 234. The spinning cable bundle 200 then passes through a canal of

cancellous bone bounded by cortical bone. This canal is made up of softer cancellous bone, and the flexible nature of the cable bundle enables the bundle to follow the path of the softer cancellous bone. This path will be followed even if the surgeon errs by angling the cable guide tube 218 slightly away from the desired axis of the pedicle
5 medullary canal.

The bore that is formed by the advancing cable bundle 200 may be slightly larger than the diameter of the cable bundle spaced from its distal end. This is shown in Figure 16 in which the individual cables 202 at their ends 242 may expand slightly under centrifugal force or due to bottoming out of the cable ends against the floor of the
10 hole being drilled, or both. As a result, the diameter of the bore hole 244 may be slightly larger than the diameter of the cable bundle 200 spaced proximally from the end 242 to provide clearance for debris to escape from the hole. As mentioned above in connection with single cable cutting elements, the diameter of the bore 244 may thus be controlled by adjusting a number of variables including the rotational speed of the
15 bundle, the axial force imparted to the bundle end in a drilling operation, the flexibility, number and diameter of the individual cables, the clearance between the bushing and the cable bundle, etc.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made
20 without departing from the spirit of the invention and the scope of the appended claims.

Claims

1. A cutting tool comprising
an elongated, flexible cutting element having a longitudinal axis about which the cutting element may be rotated and comprising a cable or bundle of parallel cables ,
5 each cable comprising an outer layer of helically wound fibers, and cutting means disposed at the distal end of the cutting element to perform a cutting function when the cutting element is rotated,
a motor attached to said cutting element remote from its distal end for rotating the cutting element about its longitudinal axis, and
10 an elongated holder having an opening for supporting the cutting element and through which the cutting element may be advanced axially, the holder having a distal end for supporting the cutting element during a drilling operation and through which the distal end of the cutting element protrudes, the holder including a cutting element support shaped to orient the longitudinal axis of the cutting element adjacent its distal
15 end and to maintain such orientation as the cutting element is rotated and advanced in a cutting operation.
2. The cutting tool of claim 1 wherein said cables are made of superelastic alloy fibers.
3. The cutting tool of claim 1 wherein the cutting element comprises a single cable
20 and wherein the fibers are helically wound in a clockwise or counterclockwise direction toward said distal end and wherein said motor rotates the cable in the other direction.
4. The cutting tool of claim 1 wherein said fibers are formed at the distal end of the cutting element so as to themselves form said cutting means.
5. The cutting tool of claim 3 wherein one or more of said fibers define a loop
25 adjacent the distal end of the cable, the loop tending to enlarge under centrifugal force and axial compression.
6. The cutting tool of claim 3 wherein the distal end of the cable is woven to define an open basket configuration.

7. The cutting tool of claim 4 wherein said fibers are cut across their widths at an angle perpendicular to the longitudinal axis of the cutting element.
8. The cutting tool of claim 3 wherein said cable is so formed as to enable fibers adjacent the distal end of the cable to separate from each other slightly, whereby, in a drilling operation, the diameter of the hole that is drilled is slightly larger than the diameter of the cable adjacent but spaced from its distal end.
9. The invention of claim 8 wherein the cable and motor are selected so that fibers at the distal end of the cable are enabled to separate from each other under centrifugal force as the motor rotates the cable.
10. The invention of claim 8 wherein the cable is so formed as to enable the fibers adjacent the distal end of the cable to bow outwardly as the cable is axially compressed against a floor of a bore.
11. The cutting tool of claim 1 wherein said elongated holder includes a supporting surface positioned to contact and support said cable at one or more points along its length.
12. The cutting tool of claim 11 wherein said elongated holder has a hollow interior with interior walls thereof forming said supporting surface.
13. The cutting tool of claim 11 wherein said elongated holder comprises a tubular support housing and supporting said cable throughout substantially its entire length.
14. The cutting tool of claim 1 including a separate drill bit secured to the distal end of the cable.
15. The cutting tool of claim 4 wherein said flexible cutting element comprises a bundle of cables so formed as to enable individual cables adjacent the distal end of the cutting element to separate from each other slightly, whereby, in a drilling operation, the diameter of the hole that is drilled is slightly larger than the diameter of the cable bundle adjacent but spaced from its distal end.
16. The cutting tool of claim 15 wherein the flexible cutting element and motor are selected so that cables at the distal end of the cutting element are enabled to separate

from each other under centrifugal force as the motor rotates the cutting element.

17. The cutting tool of claim 15 wherein the cutting element is so formed as to enable cables adjacent their distal ends to bow outwardly as the cable bundle is axially compressed against a floor of a bore.

5 18. The cutting tool of claim 1 including a drive tube gripping said cutting element and rotationally driven by said motor, said drive tube being telescopically moveable with respect to said elongated holder so that movement of the drive tube distally with respect to the elongated holder causes said cutting element to protrude from the cutting element support.

10 19. Method for drilling a hole through animal tissue comprising
providing a drill including an elongated, flexible cutting element having a longitudinal axis about which the cutting element may be rotated and comprising a cable or bundle of parallel cables, each cable comprising an outer layer of helically wound fibers, cutting means disposed at the distal end of the cutting element to perform a
15 cutting function when the cutting element is rotated about its longitudinal axis, and an elongated holder having an opening through which the cutting element may be advanced axially, the holder having a distal end for supporting the cutting element during a drilling operation and through which the distal end of the cutting element protrudes, the holder including a cutting element support shaped to orient the longitudinal axis of the
20 cutting element adjacent its distal end and to maintain such orientation as the cutting element is rotated and advanced distally,

rotating said cutting element about its longitudinal axis while continuously maintaining the cutting means at least partially within the hole being drilled, whereby the wall of the hole being drilled serves to support the cutting means so
25 that the latter advances through the tissue.

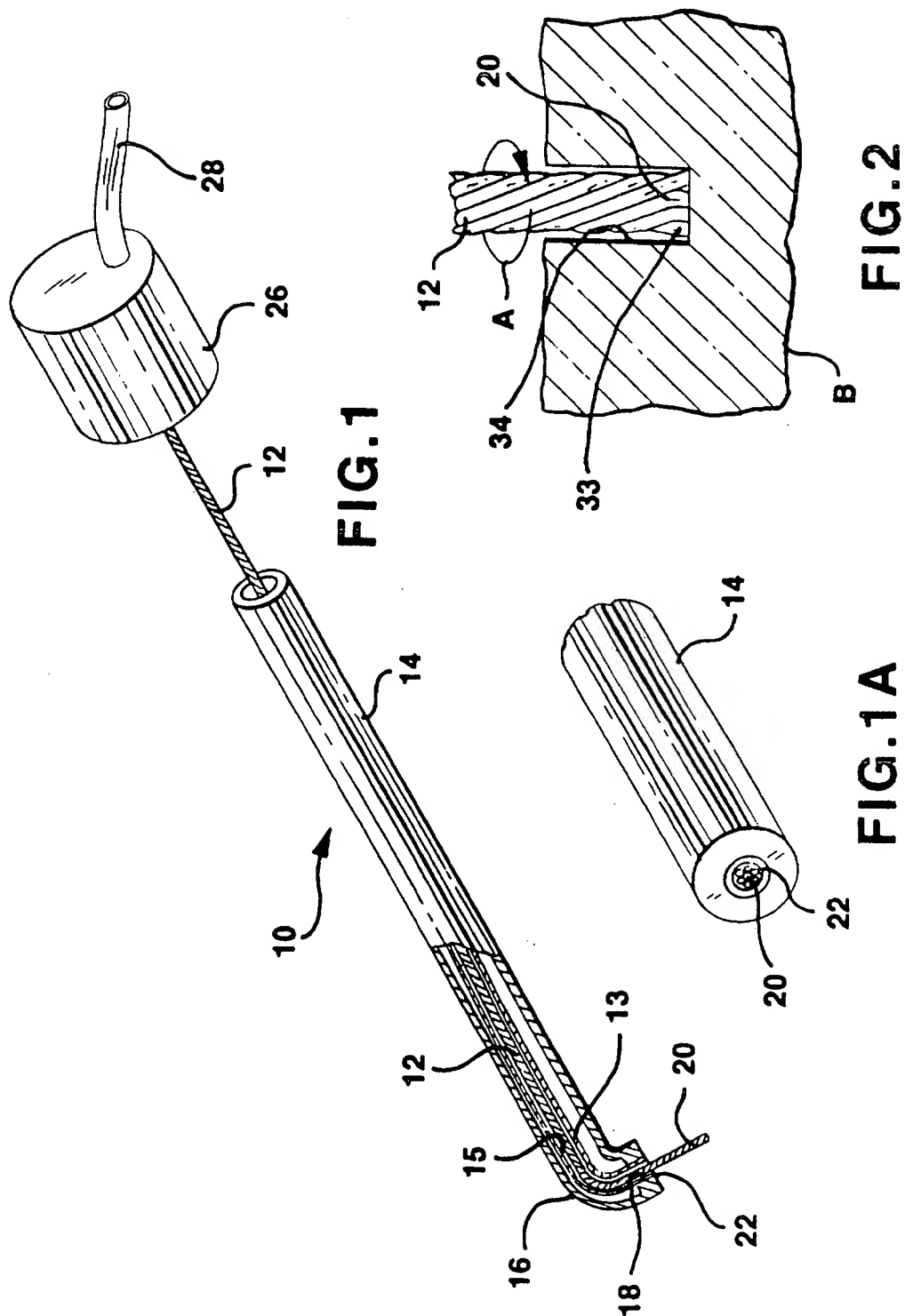
20. The method of claim 19 wherein the tissue is bone.

21. the method of claim 19 wherein the tissue is soft tissue.

22. The method of claim 20 wherein said fibers are formed at the distal end of the cutting element so as to themselves form said cutting means, and wherein said cutting element is rotated so that fibers at the distal end of the cutting element separate from each other so as to drill a hole in said bone of a diameter larger than the diameter of the cutting element adjacent but spaced from its distal end.
23. In a surgical procedure, a method for fastening an intramedullary rod to the bone within which the rod is received, comprising
- providing a drill including an elongated, flexible cutting element having a longitudinal axis about which the cutting element may be rotated and comprising a cable or bundle of parallel cables, each cable comprising an outer layer of helically wound fibers, and cutting means disposed at the distal end of the cutting element to perform a cutting function when the cutting element is rotated,
 - a motor attached to said cutting element remote from its distal end for rotating the cutting element about its longitudinal axis, and an elongated holder receivable in the intramedullary rod, the holder having a distal end for supporting the cutting element during a drilling operation and having an opening through which the distal end of the cutting element protrudes, the holder including a cutting element support shaped to orient the cutting element through substantially a right angle adjacent its distal end and to maintain such orientation as the cutting element is rotated and advanced distally,
 - positioning the holder in the intramedullary rod and aligning the hole in the holder with a preformed hole in the rod,
 - advancing said cutting means distally through the aligned holes in the holder and rod and against and through said bone while rotating said cutting element and continuously maintaining the cutting means at least partially within the hole being drilled,
 - locating the point of exit of the drill from the bone, and
 - inserting a screw fastener inwardly through the bone and intramedullary rod.

- 24 The method of claim 23 including the step of advancing said cutting element through soft tissues overlying said bone and through the skin.
25. The method of claim 23 wherein said fibers are formed at the distal end of the cutting element so as to themselves form said cutting means, and wherein said cutting
5 element is rotated so that fibers at the distal end of the cutting element separate from each other so as to drill a hole in said bone of a diameter larger than the diameter of the cutting element adjacent but spaced from its distal end.

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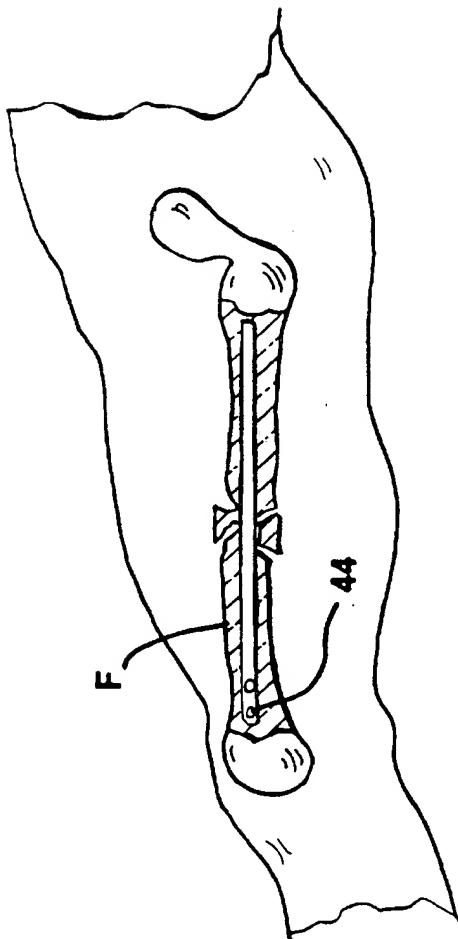


FIG. 3

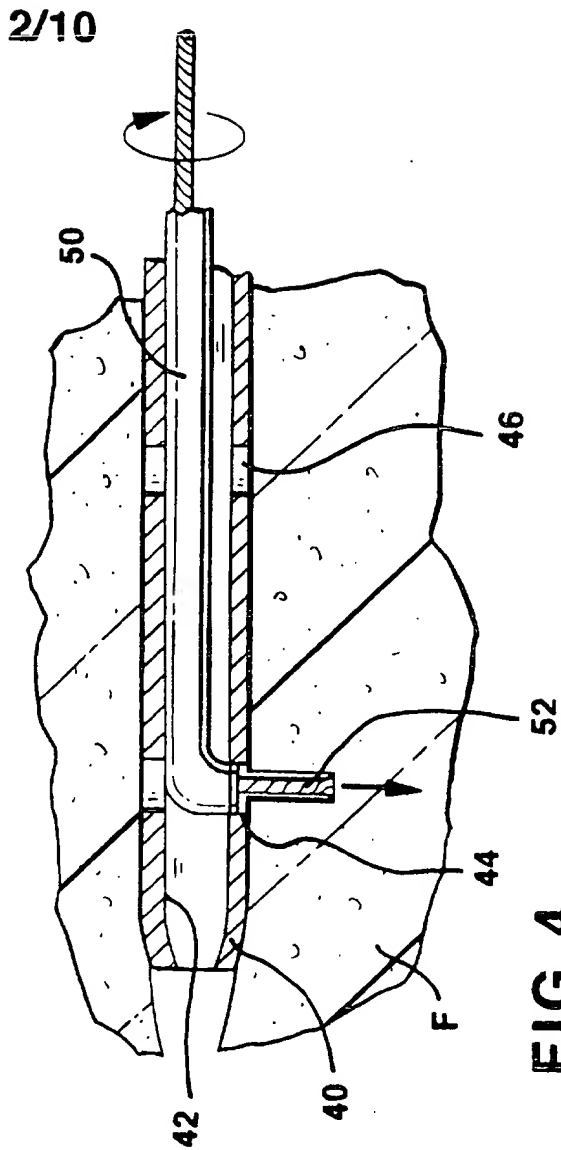


FIG. 4

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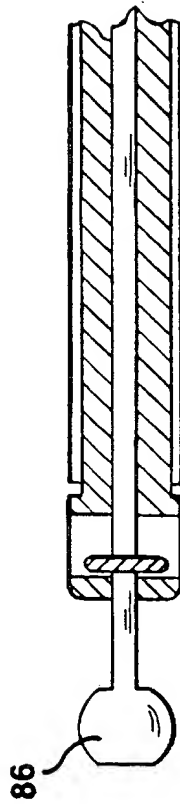


FIG. 6A

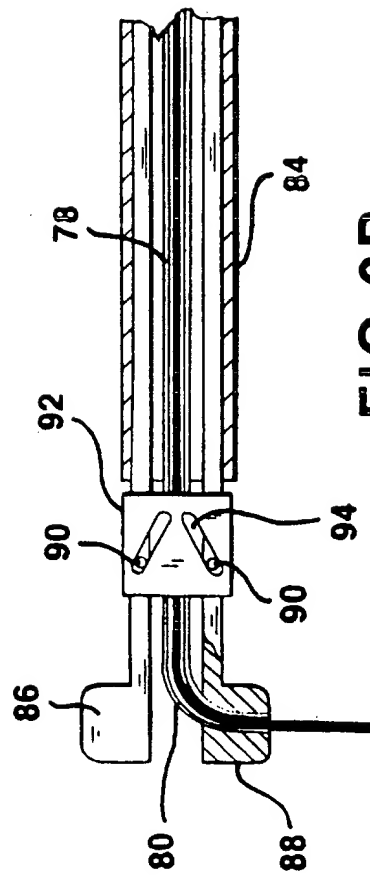
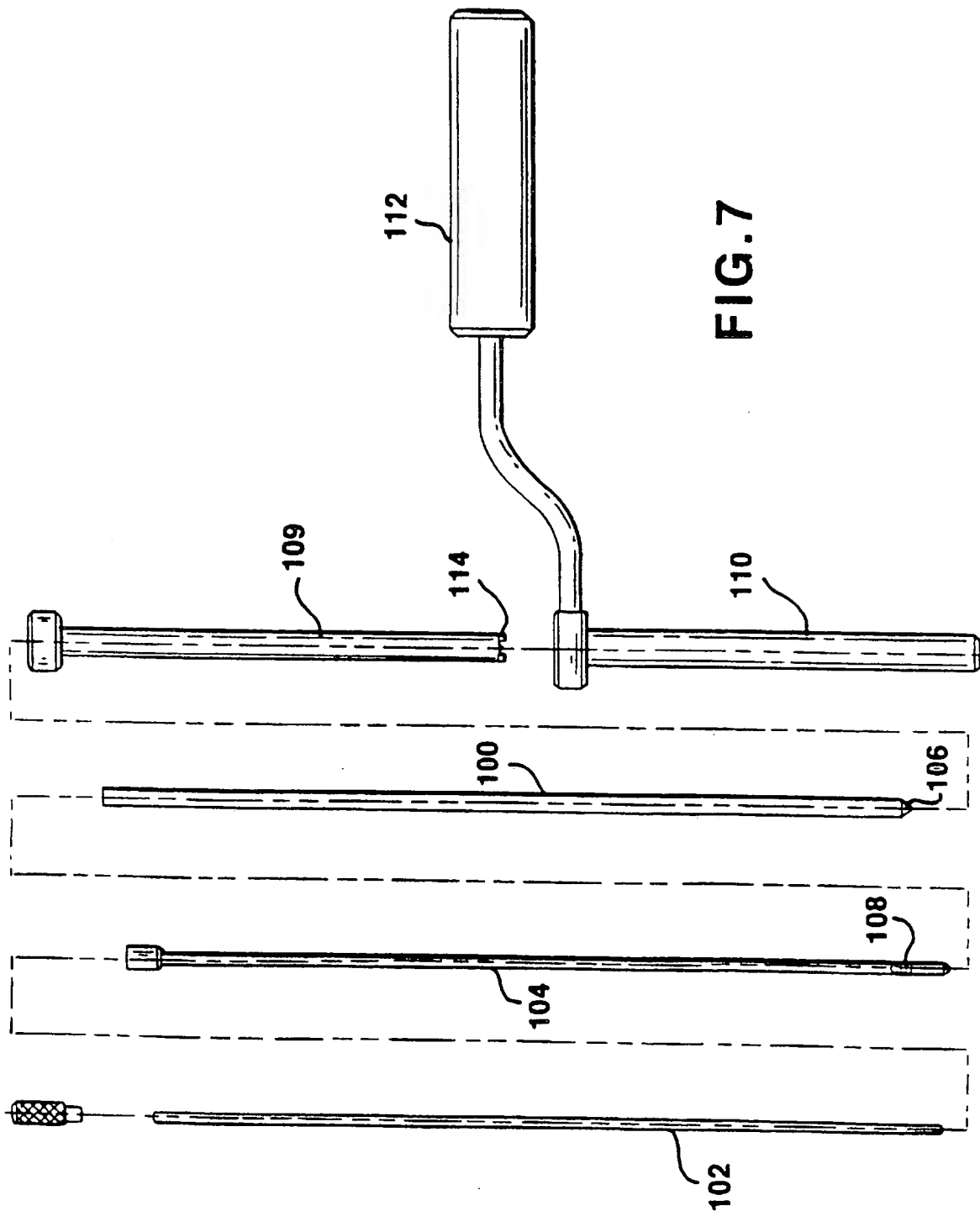


FIG. 6B

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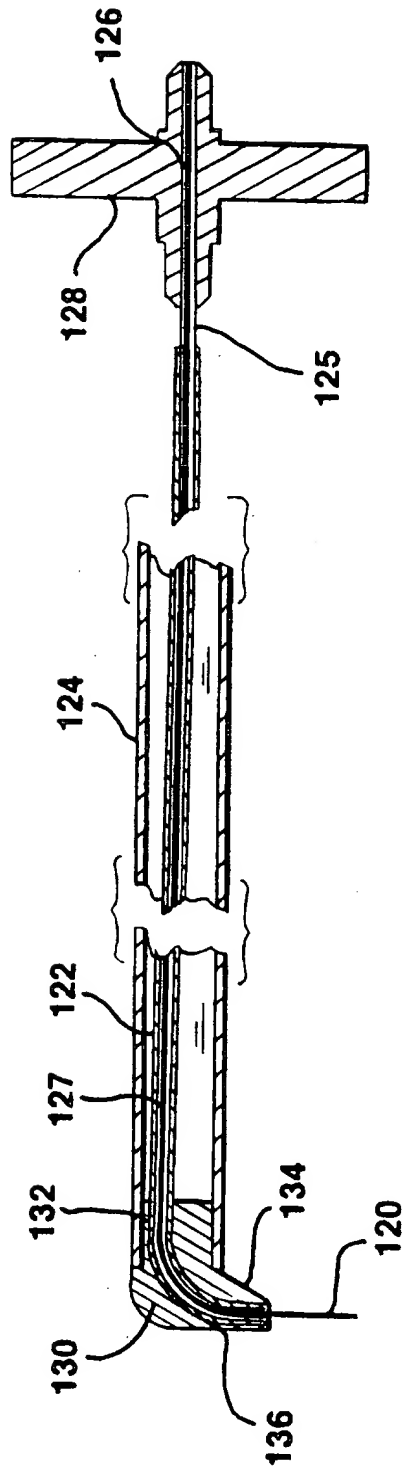


FIG. 8



FIG. 8A

7/10

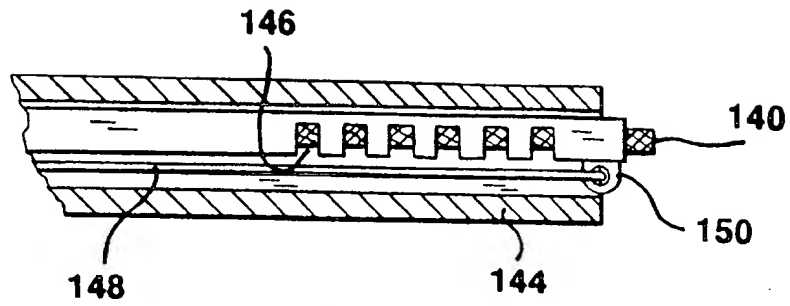


FIG. 9A

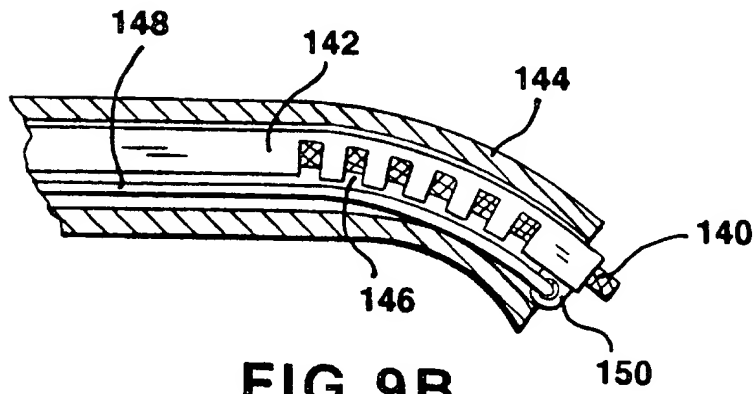


FIG. 9B

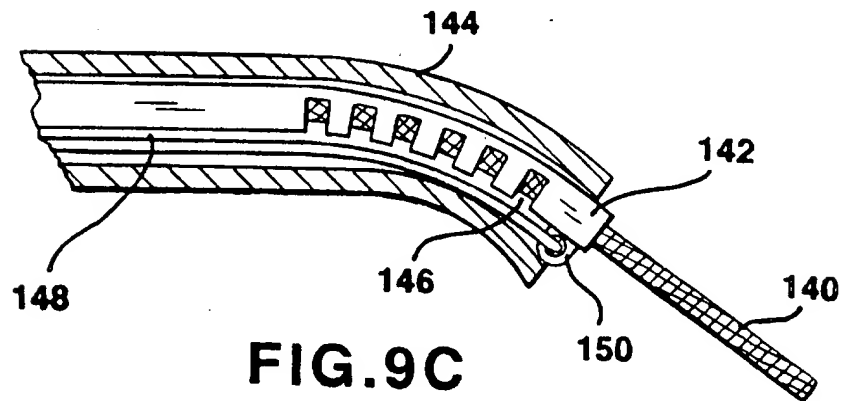
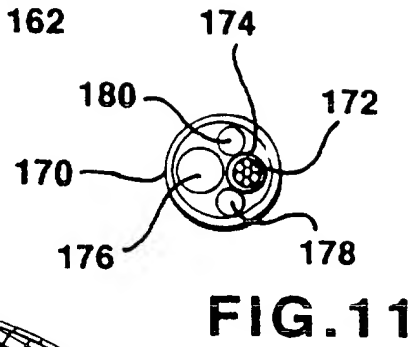
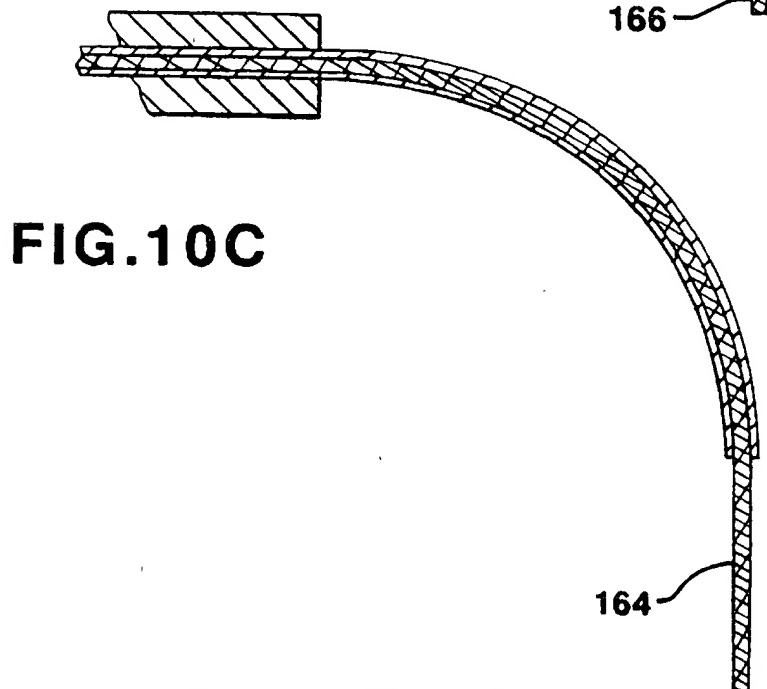
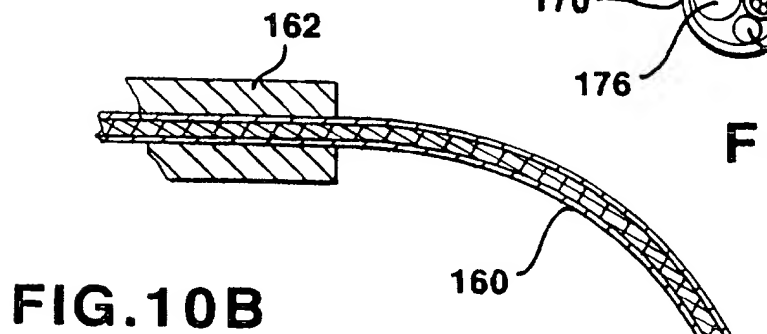
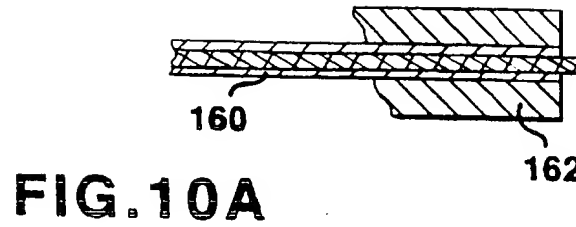


FIG. 9C

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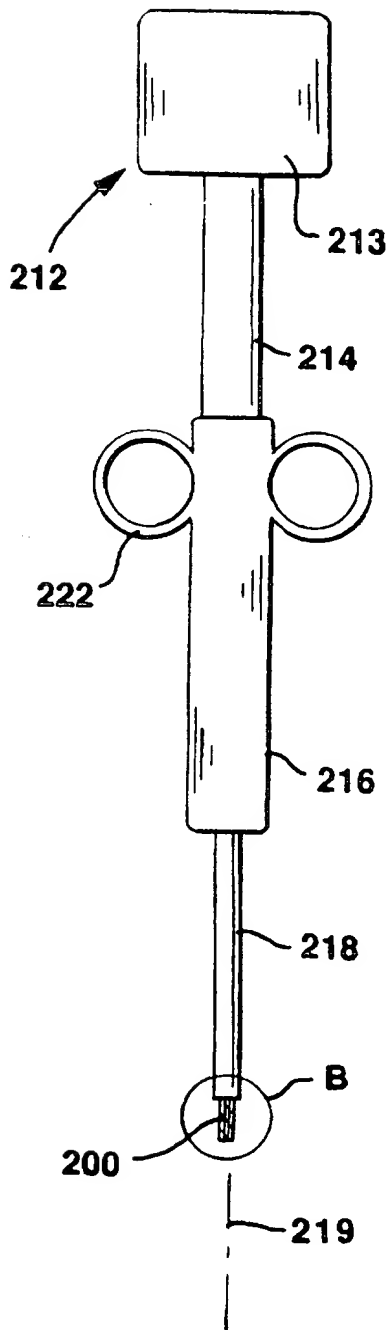


FIG. 12

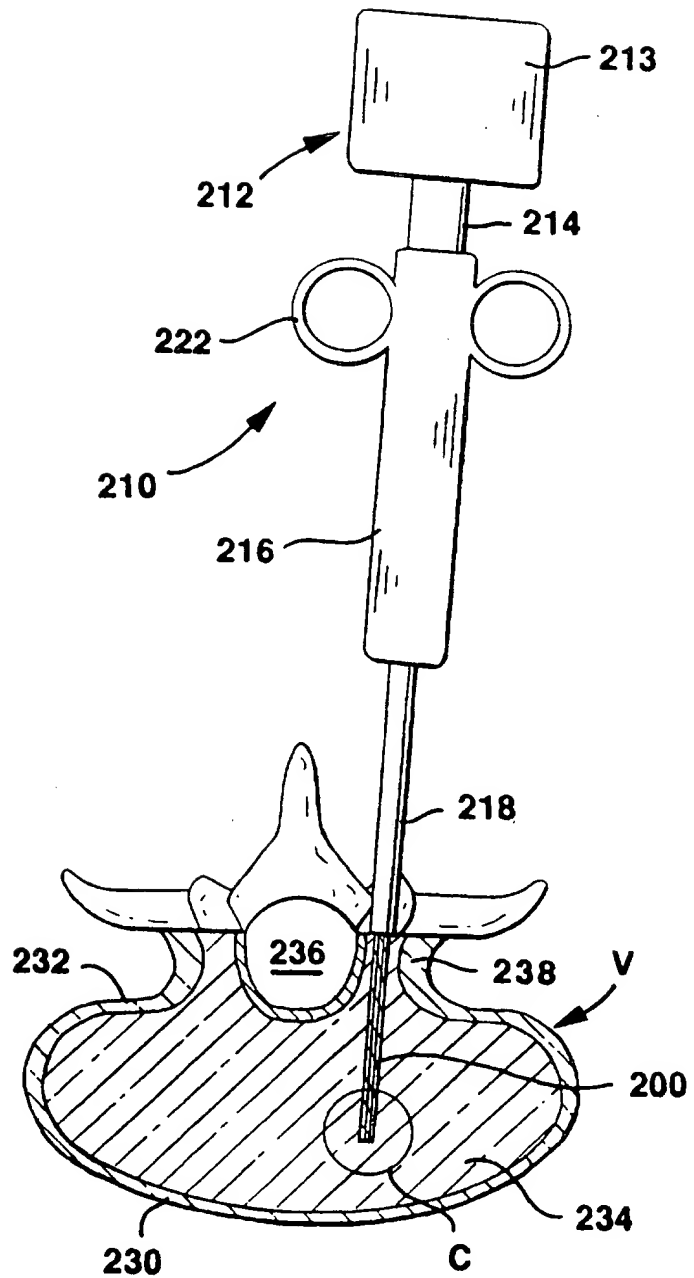


FIG. 13

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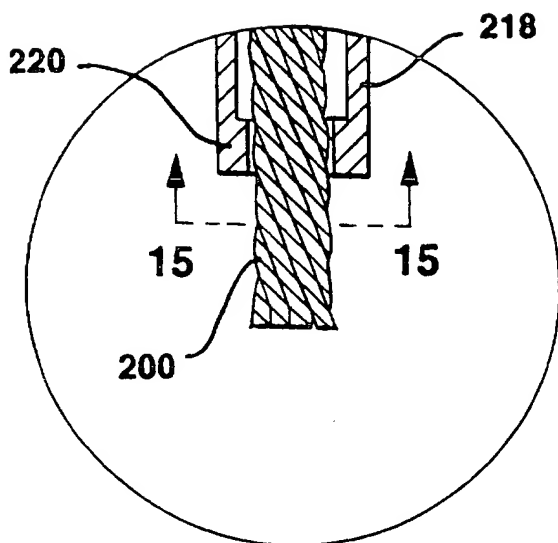


FIG. 14

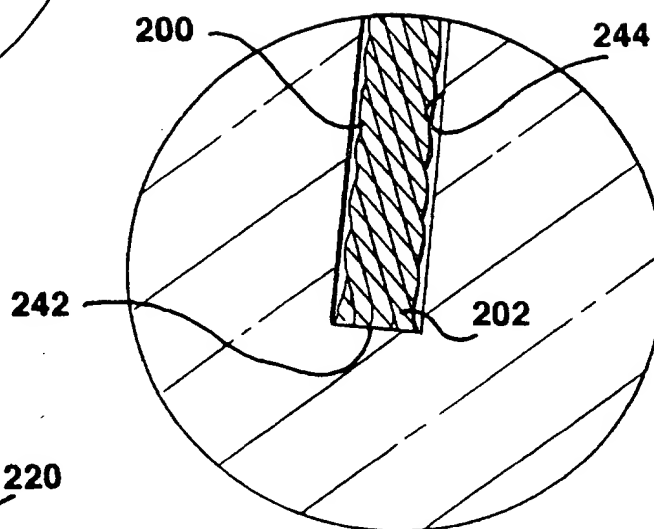


FIG. 16

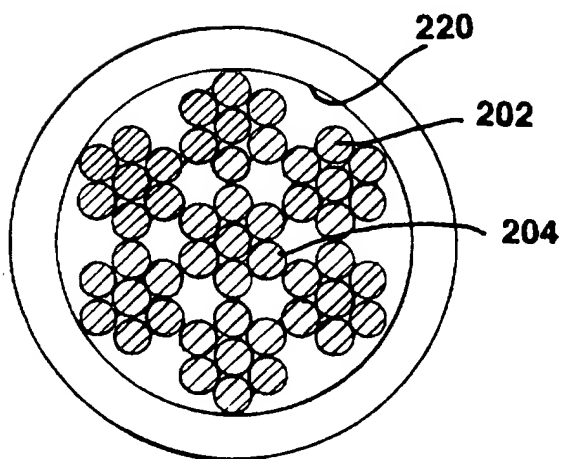


FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/03211

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/32 A61B17/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61C B23B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 549 538 A (SCHADRACK III WILLIAM C ET AL) 29 October 1985 see column 5, line 37 - line 56 ---	1,11-14
A	FR 2 344 267 A (ULRICH MAX) 14 October 1977 see the whole document ---	1,11-13
A	US 5 330 468 A (BURKHART STEPHEN S) 19 July 1994 cited in the application see the whole document ---	1
A	US 4 926 860 A (STICE JAMES D ET AL) 22 May 1990 cited in the application see the whole document -----	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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P document published prior to the international filing date but later than the priority date claimed

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Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

23 June 1997

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/03211

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 19-25
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 97/03211

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4549538 A	29-10-85	NONE	
FR 2344267 A	14-10-77	CH 610754 A	15-05-79
US 5330468 A	19-07-94	NONE	
US 4926860 A	22-05-90	NONE	